



US Environmental Protection Agency Office of Pesticide Programs

Suggested Format for Acute Toxicity Studies

February 2001

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Suggested Format for

Acute Toxicity Studies

The purpose of this document is to suggest the format for final reports (right column) and to provide instructions for the creation of PDF Version 1.3 electronic submission documents (left column.) Regarding PDF, both “bookmarks” and “links” are referenced. Bookmarks and links are similar in function in that both provide the reader with a way to move efficiently through a document as well as across documents. Bookmarks are a type of link that appear in the navigation pane on the left side of the PDF Reader user screen. Links appear within the body of a document as blue text. They permit the reader to jump to other locations with related information in the same document or other electronic documents.

The same format is appropriate for [oral](#), [dermal](#), [primary eye irritation](#), and [skin irritation](#) studies. Slightly different formats are appropriate for [acute toxicity - inhalation](#) and [skin sensitization](#) study reports.

ACUTE ORAL AND DERMAL; PRIMARY EYE IRRITATION AND SKIN IRRITATION STUDIES	
Instructions to Create PDF	Document Format
Create Bookmarks for each item in the Document Format column.	<ul style="list-style-type: none">• Study Title Page,• Statement of Data Confidentiality, <i>No confidentiality claims can be made for electronically submitted studies at this time,</i>• GLP Statement,• QA Statement.
Create bookmarks for each item in table of contents.	<ul style="list-style-type: none">• Table of Contents.
Create links in summary to related text and tables in body of study report or appendices.	<ul style="list-style-type: none">• Executive Summary,<ul style="list-style-type: none">- Summary of Materials and Methods,- Summary of Results.• Test Material Identification,• Test Animal Identification,• Test Material Administration.
Create links to related text, tables, or appendices.	<ul style="list-style-type: none">• Results,<ul style="list-style-type: none">- Mortality,- Clinical Observations,- Gross Necropsy,• Body Weights,• Deviations,• Tables.

ACUTE INHALATION TOXICITY STUDIES	
Instructions to Create PDF	Document Format
Create Bookmarks for each item in the Document Format column.	<ul style="list-style-type: none">• Study Title Page,• Statement of Data Confidentiality <i>No confidentiality claims can be made for electronically submitted studies at this time,</i>• GLP Statement,• QA Statement.
Create bookmarks for each item in table of contents.	<ul style="list-style-type: none">• Table of Contents.
Create links in summary to related text and tables in body of study report or appendices.	<ul style="list-style-type: none">• Executive Summary,<ul style="list-style-type: none">- Summary of Materials and Methods,- Summary of Results.• Test Material Identification,• Test Animal Identification,• Method,<ul style="list-style-type: none">- Ambient Conditions,- Exposure Description (Chamber/Period),- Atmospheric Generation Model,- Chamber Concentration Measurements,- Particle Size Evaluation.
Create links to related text, tables, or appendices.	<ul style="list-style-type: none">• Results<ul style="list-style-type: none">- Mortality,- Exposure Concentration,- MMAD/GSD,- Clinical Observations,- Gross Necropsy.• Body Weights,• Deviations,• Tables.

SKIN SENSITIZATION STUDIES	
Instructions to Create PDF	Document Format
Create Bookmarks for each item in the Document Format column.	<ul style="list-style-type: none">• Study Title Page,• Statement of Data Confidentiality, <i>No confidentiality claims can be made for electronically submitted studies at this time.</i>• GLP Statement,• QA Statement.
Create bookmarks for each item in table of contents.	<ul style="list-style-type: none">• Table of Contents.
Create links in summary to related text and tables in body of study report or appendices.	<ul style="list-style-type: none">• Executive Summary,<ul style="list-style-type: none">- Summary of Materials and Methods,- Summary of Results.• Test Material Identification,• Test Animal Identification (Test, Naive, Control),• Primary Irritation Screening,• Test Material Administration (Induction),• Test material Administration (Challenge/Rechallenge).
Create links to related text, tables, or appendices.	<ul style="list-style-type: none">• Results (Test material and Naive control)<ul style="list-style-type: none">- Induction,- Challenge.• Positive Control Description/Results<ul style="list-style-type: none">- Induction,- Challenge.• Body Weights,• Deviations,• Tables.